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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,561	08/13/2001	Gary James Bridger	391442001122	4067

7590 03/03/2004

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,561

Applicant(s)

BRIDGER ET AL.

Examiner

Brenda L. Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39, 40, 42 and 45-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 39, 45 and 47 is/are rejected.
- 7) ☒ Claim(s) 40, 42, 46 and 48-50 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/3/02 & 12/11/03</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 39, 40, 42 and 45-50 are pending in the application.

This action is in response to applicant's amendment filed December 11, 2003.

Claims 42 was amended and claims 49 and 50 are newly added.

Response to Amendment

Applicant's arguments filed December 11, 2003 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 112, second paragraph rejection of claim 39, labeled paragraph c) maintained in the last office action, the applicant's remarks have been fully considered but they are not persuasive.

c) The applicant stated that he has "discovered that AMD 3100 modulate the activity of the chemokine receptor CXCR4, and thus provides a readymade treatment for any diseases later found to be mediated by CXCR4". The rejection of claim 39 is on the grounds that it is indefinite, i.e. it is not known which diseases are capable of being responsive to the chemokine receptor CXCR4. The scope of diseases and/or disorders associated with the chemokine receptor CXCR4 could alter over time. The applicant is not entitled to preempt the efforts of others.

Claim 39 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

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2. The applicant's filing of a Declaration under 37 C.F.R. § 1.131 is sufficient to overcome the 35 U.S.C. § 102, anticipation rejection of claim 39 maintained in the last office action, which is hereby **withdrawn**.

3. With regards to the applicant's claim to priority in the first line of the specification, there is no indication of the type of application, i.e. whether this application is a continuation, divisional or continuation-in-part. The applicant has inserted the following:

Cross-Reference to Related Applications

"This application is a national phase of PCT/CA99/00619, filed July 8, 1999 which claims benefit of priority from U.S. application serial number 09/111,895, filed July 8, 1998, now U.S. patent 6,506,770. The contents of this application are incorporated herein by reference."

4. The applicant's amendments are sufficient to overcome the objection to the specification, which is hereby **withdrawn**.

5. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 42, 45 and 47 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant stated that the "specification contains more than adequate written description for the disorders central nervous system developmental disease and cardiogenesis developmental disease". The applicant points to the specification at page 40, line 31, and at page 41, lines 27-28 for support. However, the line 31 on page 40 is part of a statement of utility for AMD-EXP 1, AMD-EXP 2, and AMD-EXP 3, which is as follows: Additionally, AMD-EXP 1, AMD-EXP 2,

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and AMD-EXP 3 may each be used according to the foregoing methods for the treatment of a number of chemokine-mediated diseases and conditions, including: infection with HIV or FIV; a disease by the regulation of endothelial cell function; a disease relating to vascularization of the gastrointestinal tract; haematopoiesis; or cerebellar development; a disease relating to basal leukocyte trafficking or the extravasation and tissue infiltration of leukocytes in response to inciting antigens; compound effectively binds to a chemokine receptor; of inflammatory disease; cancer; central nervous system developmental disease; HIV; FIV; vasculature development disease; cardiogenesis developmental disease; haematopoiesis and other chemokine mediated diseases or disorders. Lines 27-28 on page 41 is part of a statement of utility for AMD-EXP 2, which is as follows: Additionally, AMD-EXP 2 may be used according to the foregoing methods for the treatment of a number of chemokine-mediated diseases and conditions, including: infection with HIV or FIV; a disease by the regulation of endothelial cell function; a disease relating to vascularization of the gastrointestinal tract; haematopoiesis; or cerebellar development; a disease relating to basal leukocyte trafficking or the extravasation and tissue infiltration of leukocytes in response to inciting antigens; compound effectively binds to a chemokine receptor; of inflammatory disease; cancer; central nervous system developmental disease; HIV; FIV; vasculature development disease; cardiogenesis developmental disease; haematopoiesis and other chemokine mediated diseases or disorders. Central nervous system developmental disease and cardiogenesis developmental disease are not described in the specification with respect to AMD 3100.

Claims 45 and 47 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For reasons of record and stated above.

6. The applicant's filing of a Declaration under 37 C.F.R. § 1.131 is sufficient to overcome the 35 U.S.C. § 102, anticipation rejections of the last office action, which are hereby **withdrawn**.

7. The applicant's filing of a Declaration under 37 C.F.R. § 1.131 is sufficient to overcome the 35 U.S.C. § 103, obviousness rejection of the last office action, which are hereby **withdrawn**.

Claim Objections

8. Claims 40, 42, 46 and 48-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting -SPE of 1624 at 571-272-0661.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner Art Unit 1624
March 1, 2004